Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of rewarming on injury outcome, injury severity and arterial blood gases of trauma patients hospitalized in emergency department

Protocol summary

Study aim

Study of the effect of rewarming on the outcome of injury, injury severity and arterial blood gases in hospitalized patients in the emergency department

Design

In this study, 70 trauma patients referred to the Mousavi Hospital of Zanjan, by using a Poisson model and a randomized block (randomized) block design with two groups of control and test in blocks of 6 whose block number Randomized random number tables, entry and arrangement of patients to each of the groups based on the criteria for entering the number of blocks, respectively.

Settings and conduct

Patients with trauma who will be admitted in the Mousavi Hospital of Zanjan after being randomly assigned to two groups, the Trauma Control usual treatment and the Test Group as intervention. Intervention is based on intervention rewarming strategies in the form of a temperature control package that includes several rewarming strategies (based on clinical parameters and active or passive techniques rewarm up with an intervention strategy for wounding the injured, avoiding the placement Getting to the cold, warm, and setting the ambient temperature, using a blanket of linen with a waterproof layer and disposable elastic cap with foil, injections of warm liquids by heating the blood and fluids by checking and recording the Signs of vital importance include central body temperature, heart rate, respiratory rate and blood pressure per hour First (every 15 minutes) and 6 hours later, until the normal temperature is reached, the test is performed for the test group. For the control group, the usual care is taken and the patient's patient care unit is installed. The research data were first collected during and after the intervention using a questionnaire prepared by the researcher including demographic and traumatic information are collected in two groups..

Participants/Inclusion and exclusion criteria

The criteria for entering the study include trauma patients aged 18-65 years old, with a central temperature of less than 38 ° C and above 28 ° C, without loss of consciousness, a transfer time to the center of less than one hour, and a higher ISS score 9 and less than 40. Exclusion criteria: progression toward severe hypothermia (body temperature below 28 ° C), exiting from the emergency room earlier than 6 hours, death less than 24 hours after admission to the emergency room, decreased GCS alertness Less than 13 at each stage of the intervention, cardiopulmonary arrest before reaching the center or at any stage of the intervention and dissatisfaction of the patient or his family.

Intervention groups

The study population consisted of all trauma patients admitted to the emergency department of Ayatollah Mousavi Hospital in Zanjan. After the random sampling (random block), the blocks were randomly assigned to control and test groups. Six blocks were selected from the random numbers table. The arrangement of patients to each group will be based on the criteria for entry in the order number of the blocks.

Main outcome variables

Injury outcome; injury severity; arterial blood gases of trauma patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151112025009N2**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rewarming on injury outcome, injury severity and arterial blood gases of trauma patients hospitalized in emergency department

Public title

The effect of rewarming on injury outcome, injury severity and arterial blood gases of trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with traumatic ranges aged 18-65 years old with a core temperature of less than 38 ° C and above 28 ° C Without loss of consciousness Transfer time to the center of less than one hour ISS score above 9 And less than 40

Exclusion criteria:

Progression to severe hypothermia (core body temperature below 28 ° C) Exits from the emergency less than 6 hours Death less than 24 hours after admission Decreased GCS awareness less than 13 At each stage of the intervention, cardiopulmonary arrest before reaching the center or at any stage of intervention and dissatisfaction of the patient or his family

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was a clinical trial with control group. The reheat approach is carried out by the researcher responsible for the study at the time until the sample size is completed. The study population consisted of all trauma patients admitted to emergency department of Ayatollah Mousavi Hospital in Zanjan. After determining the sample size, this study was performed using Poisson's model (so that according to the sample size the duration of intervention was determined) and by random sampling (block) randomized block with two groups of control and test in Blocks 6 The number of blocks from the random number table, the entry and arrangement of patients to each of the groups will be based on the criteria for entering the number of blocks, respectively. The usual care group will receive the trauma and reheat test group as intervention.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Azadi Square - Beginning of the Islamic Republic Boulevard - Central Station of Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515789589

Approval date

2017-10-03, 1396/07/11

Ethics committee reference number

IR.ZUMS.REC.1396.163

Health conditions studied

1

Description of health condition studied

Hypothermia

ICD-10 code

T68

ICD-10 code description

Hypothermia

Primary outcomes

1

Description

Determination and comparison of death rate, admission rate, hospitalization period, injury severity and arterial blood gas levels in hospitalized patients in the emergency department of Ayatollah Mousavi Hospital in Zanjan in the control and test groups.

Timepoint

Measurement of central temperature at the first hour (every 15 minutes) and 6 hours to reach normal temperature - Arterial blood gases taken at one hour and six hours after hospitalization - Measuring the deterioration of the injury with the standard ISS, RTS- Track the patients' situation after ten days of the incident

Method of measurement

Tympanic thermometer digital - Machines ABG optimedical - measure the severity of the injury criteria (Injury Severity Score Revised Trauma Score)

Secondary outcomes

1

Description

injury outcome (length of stay in hospitals, admission to the intensive care unit, death)

Timepoint

Deaths up to 10 days

Method of measurement

Medical documents

2

Description

Injury Severity

Timepoint

Admission, at the first hour, six hours later, if admitted to the special department

Method of measurement

Revised Trauma Score

3

Description

Arterial blood gas

Timepoint

Before intervention 6 and 12 hours later intervention

Method of measurement

Radial artery blood sampling

Intervention groups

1

Description

Intervention group: they will receive rewarming strategies (wear wet clothes, avoid getting cold, warm, and adjusting the ambient temperature, using a suitable blanket of linen linen with a waterproof layer, a disposable cap with a foil layer, injections of warm veins with a blood heater and liquids)according to the entry criteria.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

بخش اورژانس مرکز آموزشی درمانی آیت الله موسوی زنجان

Full name of responsible person

سارا صادقی محمدی

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The data on the primary and secondary consequences can be shared.

When the data will become available and for how long

Start of access from the second half of 1397

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

It can be used in coordination with the scientific authority

From where data/document is obtainable

mdinmohammadi@zums.ac.ir

What processes are involved for a request to access data/document

Contact by email with the scientific project manager

Comments